Remarks

Status of the Claims

Upon entry of the forgoing amendment, claims 57, 58, 70, 71, 79, 87 and 90-94 are pending in the application. Claims 57, 90 and 94 are the independent claims. Claim 90 has been amended and new claim 94 has been added.

Claim 90 has been amended according to the discussion between Applicants' representatives and the Examiners during the interview on October 6, 2010. Support for the amendment is found on page 3 line 26 to page 4, line 1 and in Example 2.

New claim 94 has been added. New claim 94 is the proposed claim 99 discussed during the interview on October 6. It is Applicants' understanding that inclusion of claim 94 is permissible since hypertriglyceridemia was an election of species.

No new matter has been added by the amendments to the claims. Accordingly, entry of these amendments is respectively requested.

Statemtents of Substance of the Interview

Applicants sincerely thank Examiner Nelson Clarence Blakely III and his supervisors, Examiners Ardin Marschel and Phyllis Spivack, for the very courteous and helpful interview granted to Applicants' representatives, on October 6, 2010. The interview summary as provided by the Examiner is correct except that the Applicants' representatives also discussed that the claims of Application No. 12/685,377, a divisional of the present application, are directed to the non-elected Group II invention of the

present application. Therefore, the obviousness-type double patenting should be overcome.

In addition, during the interview, the Examiners questioned whether administering 1-MNA^+ to dyslipidemia patients adversely affect the level of a plasma lipid component that is already in the normal range when treating an abnormal level of another plasma lipid component.

Applicants' representatives explained that it is the representatives' understanding that administering 1-MNA^+ advantageously has a "normalizing effect" on a patient's lipid profile. That is, administering the drug raises or lowers the abnormal plasma level of a lipid component toward the normal range for that component without changing the plasma level of another lipid component that is already within the normal range to be significantly outside the normal range. Applicants submit additional data demonstrating this effect in the accompany Declaration by professor Gebicki.

The rejection under 35 U.S.C. § 112, enablement

At Office action page 3, claims 90-93 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled in commensurate in scope with these claims. The Examiner acknowledges that the claims are enabled for the treatment of hypertriglyceridemia, but asserts that they are not enabled for other types of dyslipidemia such as the lipid disorder hyperapolipoprotein(B) discussed in Wanger *et al.* (Diabetes Care, 22:812-817 (1999)).

Claim 90 has been amended. Applicants' representatives and the Examiners discussed proposed claim amendments during the interview on October 6. As stated in the Examiner's Interview Summary, the Examiners were in favor of claim 90 as amended.

As acknowledged in the Office action, the specification enables a method for treating high plasma triglyceride (TG) levels or low plasma HDL levels or both in patients. In particular, Example 2 discloses clinical results demonstrating that administering 1-methylnicotinamide (1-MNA^+) to patients having abnormal plasma TG and HDL levels treated the abnormal lipid profiles in those patients by significantly lowering the TG levels and raising the HDL levels toward the normal range.

Applicants submit herewith additional clinical data further demonstrating that claim 90 and its dependent claims 91-93 are fully enabled.

Specifically, Applicants submit herewith a declaration by co-inventor professor Jerzy Gębicki under 37 C.F.R. § 1.132, showing additional clinical data of administering 1-MNA^+ to dyslipidemia patients.

As shown in Table 1 of the declaration and explained by professor Gebicki, in patients with a HDL level of < 40 mg/dL and a high TG level (between 150 mg/dL and 250 mg/dL), administering 1-MNA^+ did not reduce significantly the TG level, but an increase of the HDL level was observed (35.35 vs. 40.48 mg/dL, a 14.53% increase) after a 4-week therapy. *See* Declaration of Professor Jerzy Gebicki, Table 1 and paragraph 9.

Professor Gebicki further explains that for a group of patients who had a plasma TG level of > 200 mg/dL and a plasma HDL level of > 40mg/dL, administering 1-MNA^+ reduced the plasma TG level (328.12 vs. 267.70 mg/dL, a 18.41% decrease). In those patients increase of the HDL level was not observed after the 4-week therapy. *See* Declaration of Professor Jerzy Gebicki, Table 2 and paragraph 11.

In summary, the specification and the additional data submitted in the accompanying declaration demonstrate that administering 1-MNA^+ treats high plasma TG and/or low plasma HDL in dyslipidemia patients. Therefore, claims 90-93 are fully enabled. New claim 94 is also enabled in comsummerate to its full scope for the same reasons discussed above.

Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

The provisional obviousness-type double patenting rejection

At page 6 of the Office action, claims 57, 58, 70, 71, 79, 87 and 90-93 have been provisionally rejected under the doctrine of obviousness-type double patenting (ODP) over certain claims of Application No. 12/685,377 (the '377 application). The Examiner asserts that the claims of the applications are not distinct from each other. Applicants respectfully traverse this rejection.

The '377 application is a divisional application of the present application. In a Restriction Requirement mailed on January 29, 2009, the Examiner restricted the claims

of the present application into 2 groups. Applicants elected claims directed to Group I for further prosecution in the present application.

Applicants filed a Preliminary amendment when filing the '377 application, amending the claims of the '377 application to direct to the non-elected Group II invention from the present application. The conflicting claims of the '377 application recited in the Office action were canceled. Therefore, the provisional ODP rejection is improper. *See* MPEP § 804.01.

Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

It is respectfully believed that a full and complete reply to the Office action has been made and that this application is now in condition for examination. Early notice to this effect is respectfully requested.

Respectfully submitted,

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